DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

g1242d

MAY 15 2001

WARNING LETTER

WITH AUTOMATIC DETENTION

VIA FEDERAL EXPRESS

REF: I1-1895

Mr. Zhang Song
Engineer
TCL Holdings Co., Ltd.
No. 6 Eling South Road
Huizhou City, Guangdong Province
CHINA

Mr. John Y. Chan
BACL Engineering Manager
Bay Area Compliance Laboratory Corporation
230 Commercial Street, Suite 2
Sunnyvale, California 94086

Dear Mr. Song and Mr. Chan:

This letter notifies you that the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), disapproves the quality control and testing program for TCL Holdings Co., Ltd. This action is taken under the authority of the United States (U.S.) Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control, Section 534.

On January 16, 2001, CDRH received a radiation safety product report from Mr. John Chan, Bay Area Compliance Laboratory Corporation, submitted for TCL Holdings Co., Ltd. Ms. Debra Clingan of my staff reviewed the report and found serious deficiencies. Mr. Chan was notified, by phone, on January 31, 2001. On February 26, 2001, CDRH received another submission from Mr. Chan for the same product. The following conflicting or inadequate information was noted in the review of the product reports:

January 16 and February 26 submissions

1. Part 5.5, Hold-Down Safety Circuit - The January 16 submission states in Part 5.5 there is no hold-down safety circuit but Attachments E, F, and J refer to an x-ray protect circuit. The February 26 submission states there is a hold-down safety circuit

but Attachment J shows that no failure consideration was done in the hold-down/safety circuit area. This shows that an adequate engineering analysis was not done. Please refer to the " Reporting and Compliance Guide for Television Products" page 41.

2. Part 5.2, Attachment E, Circuit Diagram - The circuit diagram in the report is too small to identify the components.

3. Part 5.3, Attachment F - The graphs provided in Attachment F are not correctly labeled. Anode Voltage is on the top horizontal scale while the Anode Current is on the bottom horizontal scale. There is no labeling for the vertical scale.

4. Parts 5.3 and 5.6, Attachments F and J - The January 16 submission shows the data plotted for the design-center chassis power curve is higher than the data plotted for the worst-tolerance chassis power curve. Since the worst-tolerance chassis is fitted with critical components at their worst tolerance values, the graph for the worst-tolerance chassis will be higher than the design-center chassis. Also, the data from Attachment J4 (design-center chassis) does not agree with what is plotted on the graph. In the February 26 submission, it shows that the headings (design-center chassis and worst-tolerance chassis) for the two graphs were switched but the actual graphs remained the same.

5. Part 5.6, Attachment J2, Worst-Tolerance Chassis Component Information - Both reports list three critical components, [redacted], [redacted] and [redacted]. Attachment E, critical component list, contains [redacted] critical components. Were all critical components considered during your engineering analysis?

6. Part 6.15, Instrumentation - Both reports list different instruments for x-radiation production testing. What instruments does TCL Holdings use to conduct their testing?

7. Part 6.15, Attachment M - The January 16 submission contains the calibration certificate for the [redacted] serial number [redacted], calibrated 08/15/00. The February 26 submission contains the calibration certificate for the [redacted] serial number [redacted], calibrated 02/16/00. Again, what instrument does TCL Holdings have?

8. Part 6.14, Attachment P - This attachment is inadequate in both submissions. There are no instructions for introducing the worst-case fault found during the engineering analysis. Phase III x-radiation production testing is introduction of the worst-case fault and adjustment of all user and service controls. This is a requirement of 21 Code of Federal Regulations (CFR) 1020.10(c)(3)(iii). Attachment P is missing the instructions for daily checks of the qualitative x-ray survey meter, and the operation of the qualitative x-ray survey meter is incorrect. Also, there is no mention of the reject limit or what steps the test technician should take if the reject limit is met. Please review pages 36 and 37 of the " Reporting and Compliance Guide for Television Products."

Based on the review of the two submissions, CDRH concludes that TCL Holdings fails to establish that it has in place a quality control and testing program that assures compliance with the applicable performance standards, 21 CFR 1010.2(c) and 1020.10.

The disapproval of the testing program means that TCL Holdings Co., Ltd., is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,

2. introducing or importing products into the U.S. commerce which bear false and misleading certification; that is, products certified under the testing program which has been disapproved, and

3. introducing or importing into U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

The FDA may initiate regulatory action against any person who violates Section 538, including an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

The Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) or to furnish or preserve any information required pursuant to Section 537(f).

Moreover, under Section 536(a) of the Act, FDA may refuse entry or importation into U.S. commerce of any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved. Therefore, TCL Holdings Co., Ltd., is being placed on the import detention list and its products will be automatically detained at port of entry until the quality control and testing program disapproval is rescinded. A copy of this letter will be placed on the FDA's world wide web home page under Monthly Import Detention List and Warning Letters: http://www.fda.gov.

To resolve this matter, you must respond to the eight deficiencies listed in the letter. The CDRH will advise you whether your submittal is satisfactory and when introduction of certified products into U.S. commerce may begin.

We are also requesting that TCL Holdings Co., Ltd., provide a sample of the final product for compliance testing by the FDA's Winchester Engineering and Analytical Center (WEAC). Results of the compliance testing will be closely compared against the product design, labeling, and x-radiation safety information given in the product report and supplemental report. Ms. Debra Clingan of my staff will contact you with instructions on when and where to send the sample.

You may submit your response to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance (HFZ-342), Division of Enforcement III, 2098 Gaither Road, Rockville, Maryland 20850. In your response, please reference case I1-1895 and this letter.

If you have any questions regarding this warning letter, you may contact Ms. Debra Clingan of my staff at (301) 594-4654 or by facsimile (301) 594-4672.

Sincerely yours,

Gladys Rodriguez for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health